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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/943,688	ROSTAMI et al.
Examiner	**Art Unit**
Michele Flood	1654

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 17, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group I, Claims 1-13, in Paper No. 7 is acknowledged. Acknowledgment is made of Applicant's cancellation of Claims 14-19 without prejudice.

Information Disclosure Statement

The information disclosure statement filed July 10, 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because: No copy of either the cited patents or non-patent literature references were received. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating chronic inflammation in a patient with disclosed inflammatory autoimmune diseases comprising administering to the patient an effective amount of Bowman Birk Inhibitor (BBI) extracted from soybeans, does not reasonably provide enablement for a method of treating chronic inflammation in a patient with any and all inflammatory autoimmune diseases comprising the administration of an amount of any and all Bowman Birk Inhibitors effective to prevent chronic inflammation and to prevent demyelination of the nerve tissue of the patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to a method for treating chronic inflammation in a patient with inflammatory autoimmune disease comprising administering to the patient an amount of Bowman Birk Inhibitor effective to reduce, inhibit, suppress or prevent the chronic inflammation. The claims are further directed to the method of claim 1, wherein the chronic inflammation is inflammation of neural tissue, wherein the neuroinflammation affects the central nervous system or peripheral nervous system of the patient, wherein demyelination of the nerve tissue of the

patient is reduced, inhibited, suppressed or prevented, and wherein the patient is affected by the disease selected from the group consisting of Multiple Sclerosis, Guillain Barre Syndrome and rheumatoid arthritis. The claims are further directed to the method of claim 1, wherein the patient is a mammal, wherein the patient is a human, wherein the Bowman Birk Inhibitor is administered orally, wherein the Bowman Birk Inhibitor is administered as Bowman Birk Inhibitor Concentrate, wherein the Bowman Birk Inhibitor is provided as an enriched concentrate extracted from a legume, wherein the Bowman Birk Inhibitor is provided as an enriched concentrate extracted from soybeans, wherein the Bowman Birk Inhibitor is administered to the patient with a carrier therefor, and wherein the Bowman Birk Inhibitor is administered with another therapeutic agent, drug, medicament, or therapy.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The specification broadly discloses a method for treating chronic inflammation in a patient with inflammatory autoimmune disease comprising administering to the patient an amount of Bowman Birk Inhibitor effective to reduce, inhibit, suppress or prevent the chronic

inflammation. While the specification does demonstrate a method for administering effective amounts of a soybean Bowman Birk Inhibitor Concentrate (BBIC) to Lewis rats induced with Experimental Allergic Neuritis (EAN - an animal model of autoimmune peripheral nerve demyelinating disease having clinical, pathological and electrophysiological similarities to human Guillain-Barre Syndrome (GBS)) to reduce the clinical signs of EAN, the specification does not disclose a method for treating chronic inflammation in a patient with any and all inflammatory autoimmune diseases comprising administering an amount of any and all Bowman Birk Inhibitors obtained from any and all legume sources as broadly claimed. For instance, on page 21, lines 30-31 bridging page 22, lines 1-16, Applicant discloses that the oral administration of 200 mg of BBIC in saline to Lewis rats induced with EAN reduced the time and severity for the presentation of the clinical symptoms of EAN. On page 25, lines 7-25, Applicant discloses that the oral administration of 500 mg/ml of BBIC in water to EAN-induced Lewis rats decreased clinical severity and pathological manifestations of EAN, and reduced inflammatory cell accumulation in the peripheral nerve tissue. In another animal model having similarities to human Multiple Sclerosis (MS), Experimental Autoimmune Encephalomyelitis (EAE), Applicant discloses, "[O]rally administered BBIC was seen to inhibit both the clinical and pathologic manifestations of EAE in Lewis rats inoculated with myelin basic protein (MBP) in complete Freund's adjuvant (FIGs 9, 10)", on page 28, lines 14-16. With particular regard to Figure 10, Applicant urges that the illustrated data shows the beneficial functional effect for the administration of BBIC, i.e., "Inflammatory demyelination in the CNS of BBIC-treated and -

untreated EAE Lewis rats". However, the graphic details of Figure 10 are not well defined for interpretation of the results of the experimental data. For example, it is unclear as to what the asterisks (*) or as to what the terms "sc(c)", "sc(t)","sc(l)", and "sc(s)" refer. Thus, it is uncertain as to whether the graphic details of Figure 10 truly depict that the administration of BBIC to EAE Lewis rats treats or prevents demyelination in EAE Lewis rats. Finally the Office notes that while Applicant has demonstrated the clinical effects for the administration of the claim-designated BBIC to animal models induced with either EAE or EAN, Applicant has not demonstrated the administration of either BBI or BBIC to an animal model induced with the inflammatory autoimmune disease rheumatoid arthritis which is not an neuroinflammatory disease like either Multiple Sclerosis or Guillain Barre Syndrome. Hence, Applicant has reasonably demonstrated that the claimed Bowman Birk Inhibitor as an enriched concentrate extracted from soybeans, i.e., soybean BBIC, is useful as a therapeutic agent for treating chronic inflammation in a patient with the neuroinflammatory autoimmune diseases, MS and GBS, comprising administering an effective amount of soybean BBIC to reduce, inhibit, suppress, and/or reduce the risk thereof. However, the claims encompass using the claimed composition to prevent chronic inflammation which is clearly beyond the scope of the instantly disclosed invention. Even more, the claims also encompass using an amount of Bowman Birk Inhibitor obtained from any and all legume sources to treat or prevent demyelination of nerve tissue, which is also beyond the scope of the instantly disclosed invention. As drafted, Claim 4 reads on preventing demyelination of nerve tissue in patients with inflammatory autoimmune disease

which in essence reads on the prevention of active or pre-existing conditions of demyelinating inflammatory autoimmune diseases, such as Multiple Sclerosis and Guillain Barre Syndrome. The Office notes that these disease conditions are recognized in the art of medicine as diseases which are difficult to treat, much less prevent. The difficulty of treating and/or preventing demyelination and its associated chronic inflammation in the aforementioned disease conditions are also well known in the art as clinical and pathological manifestations of inflammatory autoimmune diseases which are very difficult to control, much less prevent. Even Applicant readily admits on page 8, lines 1-5, that the state of the art, at the time the invention was made, did not recognize the administration of therapeutic compositions which controlled the disease conditions of inflammatory autoimmune diseases, such as Multiple Sclerosis: "Current therapeutic approaches to MS, such as treatment with glatiramer or beta-interferon (INF-β) have resulted in only relatively modest benefits. However, the disease is not well controlled." Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic", especially with respect to preventing chronic inflammation associated with demyelinating neuroinflammatory autoimmune diseases such as Multiple Sclerosis and Guillain Barre Syndrome, and inflammatory autoimmune diseases, such as rheumatoid arthritis. Thus, while it may be possible that the disclosed Bowman Birk Inhibitor or Bowman Birk Inhibitor Concentrate obtained from soybeans could be useful for a limited number of disclosed inflammatory autoimmune diseases, it seems unlikely that the claimed method of treatment could be used comprising the administration of an amount of

Bowman Birk Inhibitor from any and all legumes effective to reduce, inhibit, suppress or prevent chronic inflammation and/or demyelination of the nerve tissue in any and all active cases of inflammatory autoimmune diseases, as broadly claimed.

Inventions targeted for therapy in living subjects should provide evidence because of the unpredictability in biological responses to therapeutic treatments. Claims drawn to pharmaceutically acceptable compositions and methods of administering compounds to living subjects which would in effect 'prevent' the condition from happening require supporting evidence which clearly define the ingredients or constituents therein and supporting data because of the unpredictability in biological responses to therapeutic treatments or therapeutic prophylaxis. In order to enable the skilled artisan to practice the invention as claimed, Applicant would have to demonstrate the functional effect and describe the therapeutic effect or prophylactic effect, and describe the effective amounts of each ingredient for the administration of the composition intended for a therapeutic treatment of prophylaxis. There is no guidance in the specification, other than the administration of the claim-designated BBIC for treating and/or improving chronic inflammation in a patient with inflammatory autoimmune diseases which correlate with the animal disease-models for human Guillain Barre Syndrome and Multiple Sclerosis. The instant application neither provides a working example providing data which shows that either BBI or BBIC of the instant claims would indeed prevent an inflammatory event or prevent demyelination of nerve tissue in the claimed designated disease disorders. In the absence of statistically significant data, the assertions that the instant invention works are not

believable on its face in view of contemporary knowledge in the art. Moreover, upon a thorough reading of the specification as filed, the worker of ordinary skill in the art is not provided with an adequate definition of the term "inflammatory demyelination" as disclosed in the title of Figure 9. Thus, Applicant has not demonstrated the claimed functional effect of preventing chronic inflammation in any and all inflammatory autoimmune diseases, said process comprising administering an amount of any and all Bowman Birk inhibitors, i.e., any and all Bowman Birk Inhibitors obtained from any and all legume sources. The Office notes that on page 17, lines 15 to page 18, lines 1-8, Applicant discloses other plant members of the legume family which can be used in the making of enriched BBI concentrates for use in the instantly claimed invention. The Office also notes that Applicant discloses that the resulting concentrates may not have the same CI (chymotrypsin inhibitor) values as soybean BBIC, and that "the key factor is that there is some chymotrypsin inhibition." The Office further notes that Applicant readily admits that the state of the art at the time the invention was made "associated BBI/BBIC treatment of animals has been that of causing toxicity to the developing embryo when injected at an extremely high level into pregnant mice (Kennedy, 1993 A-C; Kennedy, 1994)." Given that Applicant discloses that the instantly disclosed soybean BBIC has increased chymotrypsin inhibitory activity and reduced trypsin inhibitory activity (see page 16, lines 15-16 of the instant specification) and that not all resulting legume concentrates may have the same CI value as soybean BBIC, and given that "the resulting concentrate (of legume products other than the demonstrated soybean BBIC) would be quantifiable in CI units", it is not clear from Applicant's disclosure that adjusting the CI units of

other legume concentrates to correlate with the CI units of the disclosed enriched soybean BBI concentrate would not cause toxicity when administered to animals or even provide the same claimed functional effect for treating chronic inflammation in a patient with inflammatory autoimmune disease. Finally, given Applicant's admission that current therapeutic approaches for the treatment of chronic inflammation of inflammatory autoimmune diseases are modest at best in the control of the disease conditions encompassed by Claim 5, Applicant has not demonstrated the administration of an amount of any and all of either BBI or BBIC "with another therapeutic agent, drug, medicament, or therapy" which would "prevent" chronic inflammation in a patient with any and all inflammatory autoimmune diseases, as broadly claimed and as encompassed by Claim 13 of the instantly claimed invention. The Office holds or notes that in the absence of working examples for a controversial or improbable invention or results or invention that goes against the laws of nature that working examples must be present to enable the invention. Thus, Applicant has not demonstrated the claimed functional effect of treating chronic inflammation in a patient with any and all inflammatory autoimmune diseases comprising administering to the patient an amount of Bowman Birk Inhibitor obtained from any and all legume products to reduce, inhibit, suppress or prevent the chronic inflammation, and wherein demyelination of the nerve tissue of the patient is reduced, inhibited, suppressed or prevented. Accordingly, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to determine effective therapeutic amounts of the claim designated Bowman Birk Inhibitor for administering to a patient with inflammatory autoimmune

disease to provide the claimed functional effect for reducing, inhibiting, suppressing, or preventing the chronic inflammation and/or demyelination of nerve tissue, other than the aforementioned and demonstrated therapeutic treatments comprising the administration of effective amounts of Bowman Birk Inhibitor extracted from soybeans for reducing, inhibiting, suppressing, and/or reducing the risk thereof chronic inflammation in a patient.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the nerve tissue" in line 1. The claim lacks clear antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing the limitation with neural tissue.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy et al. (A) with evidence provided by Das (B), Hassig (N), and Okamoto et al. (O).

Applicant claims a method for treating chronic inflammation in a patient with inflammatory autoimmune disease comprising administering to the patient an amount of Bowman Birk Inhibitor effective to reduce, inhibit, suppress or prevent the chronic inflammation. Applicant further claims the method of claim 1, wherein the patient is a mammal, wherein the patient is a human, wherein the Bowman Birk Inhibitor is administered orally, wherein the Bowman Birk Inhibitor is administered as Bowman Birk Inhibitor Concentrate, wherein the Bowman Birk Inhibitor is provided as an enriched concentrate extracted from a legume, wherein the Bowman Birk Inhibitor is provided as an enriched concentrate extracted from soybeans, and wherein the Bowman Birk Inhibitor is administered to the patient with a carrier therefor.

Kennedy teaches a method for treating chronic inflammation in a patient with autoimmune inflammatory bowel diseases, such as ulcerative colitis and Crohn's disease, comprising administering an effective amount of either a soybean extract of Bowman Birk Inhibitor or Bowman Birk Inhibitor Concentrate. In Column 5, line 16 to Column 6, lines 1-14,

Kennedy teaches that the inflammatory bowel diseases, ulcerative colitis and Crohn's disease, are characterized by phases of chronic inflammation. In Column 6, line 21 to Column 7, lines 1-23, Kennedy teaches combining the claim designated composition BBI with conventional pharmaceutical carriers for oral administration.

Please note that both ulcerative colitis and Crohn's disease, although not taught by Kennedy, are well recognized in the art of medicine as inflammatory autoimmune diseases, as evidenced by the teachings of Das, Hassig, and Okamoto. For instance, in Column 2, lines 23-32, Das teaches ulcerative colitis as an autoimmune disease; Hassig teaches ulcerative colitis as a chronic inflammatory disease of the bowel, in the abstract and Column 1, lines 1-30; and, Okamoto teaches ulcerative colitis and Crohn's disease as autoimmune diseases. Please further note that the aforementioned secondary references were only cited so as to show the inherent characteristics of ulcerative colitis and Crohn's disease.

The reference of Kennedy et al. anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al. (A) in view of Hassig (N).

Applicant's claimed invention of Claims 1 and 6-13 was set forth above. Applicant further claims a method of claim 1, wherein the Bowman Birk Inhibitor is administered with another therapeutic agent, drug, medicament, or therapy.

The teachings of Kennedy were set forth above. Kennedy does not teach a method of treating chronic inflammation in a patient with inflammatory autoimmune disease comprising administering to the patient an amount of Bowman Birk Inhibitor effective to reduce, inhibit, suppress or prevent the chronic inflammation, wherein the Bowman Birk Inhibitor is administered with another therapeutic agent, drug, medicament, or therapy. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treating chronic inflammation in a patient with the inflammatory autoimmune diseases taught by Kennedy by adding another therapeutic agent, drug, medicament, or therapy because Hassig teaches a method of treating chronic inflammation in a patient with the autoimmune diseases, ulcerative colitis or Crohn's disease, comprising the administration of

effective amounts of immunoglobulin. At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of success to modify the method of treating chronic inflammation in a patient with the inflammatory autoimmune diseases, ulcerative colitis and Crohn's disease, as taught by Kennedy by adding the composition taught by Hassig because Hassig teaches that the successive administration of Sandoglobulin® to patients suffering ulcerative colitis and Crohn's disease provides complete and long lasting relief after only one or two infusions (see Column 2, lines 17-19; Examples, especially Example 3). Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredients in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,614,198. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps, the actual ingredients, the subjects to which the ingredients are

administered, and the claimed functional effect appear to be identical or essentially the same.

Claims 1 and 6-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,614,198. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claim is either anticipated by, or would have been obvious the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ 2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Here, claim 1 of U.S. Patent No. 5,614,198 recites a method for treating inflammatory bowel disease in an animal comprising administering an effective amount of BBI to an animal having an inflammatory bowel disease. The method of claim 1 differs from instant claims 1 and 6-11 herein that it fails to disclose a method of treating chronic inflammation in a patient with inflammatory autoimmune disease comprising administering an effective amount of Bowman Birk Inhibitor (BBI) to a patient, wherein the patient is a mammal, wherein the patient is a human, wherein the BBI is administered orally, wherein the BBI is administered as a Bowman Birk Inhibitor Concentrate, wherein the BBI is provided as an enriched concentrate extracted from a legume, and wherein the BBI is administered to the patient as an enriched concentrate extracted from soybeans. Specifically, the method of claim 1 of the patent is a one-step method of administering BBI in an amount effective to treat inflammatory bowel disease in an animal

having inflammatory bowel disease. (As set forth *supra*, the Office notes that the art of medicine recognizes the inflammatory bowel diseases disclosed by the patent, namely ulcerative colitis and Crohn's disease, constitute inflammatory autoimmune diseases which are characterized by chronic inflammation. The Office further notes that the patent specification clearly defines BBI or BBIC as a pharmaceutical composition obtained from soybeans having the same functional effect of treating chronic inflammation in a patient with inflammatory autoimmune disease.) The instant claims are obvious variants of the limitations of the patent claims, since the patent discloses a method of administering an amount of a Bowman Birk Inhibitor or Bowman Birk Inhibitor Concentrate, which is prepared using the same ingredients and the same process steps to provide the same anti-inflammatory effect to reduce, inhibit, suppress or reduce the risk of chronic inflammation in a patient with inflammatory autoimmune disease. The MPEP states that, "The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan,* 392 F.2d 1017, 157 USPQ 37 (CCPA 1968). Furthermore, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. See *In re Vogel,* 422 F.2d 438-441-42, 164 USPQ 619, 622 (CCPA 1970)." See MPEP 804.

In determining the meaning of the terms, the Office looks to the disclosure of the patent to learn whether the invention claimed in the instant application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. In review of the

patent specification at Column 6, lines 30-34 and Column 10, lines 5-10, the definition of the claim terminology "wherein the patient is a mammal" and "wherein the patient is a human" is clearly encompassed by the disclosure of the patent which discloses administration of the claim-designated pharmaceutical compositions to animals or patients that are mammal and human. With regard to "wherein the Bowman Birk Inhibitor is administered orally", the portion of the patent which discloses the definition of the oral administration of the claim-designated pharmaceutical composition is found at Column 6, lines 42-47 to Column 7, lines 1-13 and Column 10, lines 39-43, for example. With regard to "wherein the BBI is administered as a Bowman Birk Inhibitor Concentrate, wherein the BBI is provided as an enriched concentrate extracted from a legume, and wherein the BBI is administered to the patient as an enriched concentrate extracted from soybeans", the portions of the patent which disclose the definitions of the instantly claimed limitations are found at Column 1, lines 13-15; Column 2, lines 36-36; and Column 6, lines 21-34, for example. Although the Office has clearly established that the meaning of the terms chronic inflammation and inflammatory autoimmune disease are encompassed by the terms ulcerative colitis and Crohn's disease, the Office looks to the patent to determine whether the meaning of the patent claim encompasses the meaning as set forth in the instant application, i.e., "A method for treating chronic inflammation in a patient with inflammatory autoimmune disease comprising administering to the patient an amount of Bowman Birk Inhibitor effective to reduce, inhibit, suppress or prevent the chronic inflammation". At Column 5, lines 15 to Column 6, lines 1-14; Column 7, lines 24-33; and

Column 11, line 20 to Column 13, lines 1-31, the patent discloses that the administration of the claim-designated pharmaceutical composition is intended for the treatment of the inflammatory autoimmune diseases (as defined by the art of medicine as set forth above in the 102 rejection), ulcerative colitis and Crohn's disease, wherein the disclosed functional effect provided by the administration of the disclosed composition was to treat inflammation of the chronic type. Hence, the instant claims are obvious variants of the patented claim, since the patent discloses a method for treating inflammatory bowel disease in an animal comprising administering an effective amount of BBI to an animal having an inflammatory bowel disease.

Therefore, Claims 1 and 6-11 are deemed obvious variants of the limitations of the patented subject matter as per the supporting portions of U.S. Patent No. 5,614,198 and the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C Flood.

MCF

November 30, 2002